

EPA Registration No.  
66171-7  
Vol. 6



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

February 6, 2017

Tamra Barrick  
Regulatory Specialist  
Preserve International  
994 Nandino Blvd.  
Lexington, KY 40511

Subject: Notification per PRN 98-10  
Product Name: SYNERGIZE™  
EPA Registration Number: 66171-7  
Application Date: October 25, 2016  
Decision Number: 522937

Dear Ms. Barrick

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

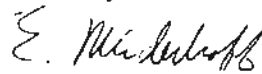
The label submitted with the application has been stamped "Notification" and will be placed in our records.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you have any questions, you may contact Mohammad Alavi at (703) 347-0522 or via email at [Alavi.mohammad@epa.gov](mailto:Alavi.mohammad@epa.gov).

Page 2 of 2  
EPA Reg. No. 66171-7  
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Sincerely,

A handwritten signature in black ink, appearing to read "E. Miederhoff".

Eric Miederhoff  
Product Manager 31  
Regulatory Management Branch I  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

**NOTIFICATION**

66171-7

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

02/06/2017

**SYNERGIZE™**

**CLEANER-DISINFECTANT**

**STAPHYLOCIDAL • PSEUDOMONACIDAL • SALMONELLACIDAL •  
VIRUCIDAL\* • PARVOCIDAL • FUNGICIDAL • ASPERGILLOCIDAL**

Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine-Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premises, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles, Veterinary Practices, Animal Care, and Animal Laboratories.

**Active Ingredients:**

Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride .....	26.00%
Glutaraldehyde.....	7.00%
Inert Ingredients:.....	67.00%
TOTAL .....	100.00%

EPA Reg. No. 66171-7

EPA Est. No. 66171-TN-001

EPA Est. No. 66171-CA-001

EPA Est. No. 61282-WI-001

EPA Est. No. 47000-IA-001

(First letter of batch number indicates establishment)

Patent Number 5,891,922

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

See left (back) (side) (right) panel (of label) (below) for additional precautionary statements

**Net Contents:**

1 gallon	(3.8L)
2.5 gallons	(9.5L)
5 gallons	(18.9L)
30 gallons	(113.6L)
55 gallons	(208L)

Code: (NI.RU) RN.RA

Label No(s): TBD

**Manufactured By:**  
Preserve International  
944 Nandino Blvd.  
Lexington, KY 40511

**PRECAUTIONARY STATEMENTS**  
**Hazards to humans and domestic animals**

**DANGER**

**KEEP OUT OF REACH OF CHILDREN.** Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Wear goggles or face shield. Wear a dust/mist/filtering respirator (MSHA/NIOSH approval number TC-21C) or a NIOSH approved respirator with any N, P, R, or HE prefilter. Wear protective clothing and rubber gloves. Prolonged or frequent repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

**ENVIRONMENTAL HAZARDS:** This product is toxic to fish, aquatic invertebrates, oysters, and shrimp. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

**FIRST AID**

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes; remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye; call a poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing; rinse skin immediately with plenty of water for 15-20 minutes; call a poison control center or doctor for treatment advice.

**IF INHALED:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible; call a poison control center or doctor for further treatment advice.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice; have person sip a glass of water if able to swallow; do not induce vomiting unless told to do so by the poison control center or doctor; do not give anything by mouth to an unconscious person.

**HOT LINE NUMBER:** Have the product container or label with you when calling a poison control center or doctor, or going for treatment. **For 24-hour emergency information on this product, call 1-800-498-5743 (US & Canada) or 1-651-523-0318 (all other areas).**

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

**DESCRIPTION**

SYNERGIZE is a multi-purpose disinfectant-cleaner. SYNERGIZE provides a broad spectrum kill of gram negative and gram positive microorganisms. SYNERGIZE provides effective disinfecting and cleaning in one operation. Synergize is effective in warm, soft or hard water (as much as 1000 ppm CaCO<sub>3</sub>) and performs especially well in areas containing 5% serum.

SYNERGIZE is for use on glazed ceramic and tile surfaces, stainless steel, aluminum, chrome, galvanized metal, tin, brass, zinc, glass, hard non-porous treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), vinyl, sealed fiberglass, Viton, ethylene propylene, nitrile, acrylic and polyurethane.

**DIRECTIONS FOR USE:**

It is in violation of Federal law to use this product in a manner inconsistent with its labeling. Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on feed, food or litter.

SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premises, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

**USE DIRECTIONS:**

To disinfect and clean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator exteriors, telephone booths and garbage cans in non-animal areas associated with the sites noted above. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) to precleaned surfaces. Apply with cloth, sponge, mop or mechanical coarse spray device, making sure all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes. All surfaces must be rinsed with clean water and allowed to dry before reuse.

**BOOT/SHOE WASH:** To prevent cross contamination into animal areas, shoe baths containing one inch of freshly made disinfecting solution must be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per gallon water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.

**VEHICLES:** To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or coarse spray system. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

**DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:**

- 1) Remove all animals and feed from the premises, vehicles and enclosures.
- 2) Empty all troughs, racks, and other feeding and watering appliances.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from walls to ceilings of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.

- 5) Thoroughly saturate with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods.
- 6) Allow all treated areas to remain in contact with this solution for at least 10 minutes.
- 7) Immerse equipment used in handling and restraining animals, forks, shovels, and scrapers used for removing manure in SYNERGIZE at a dilution of 1:256. Allow to remain in contact for at least 10 minutes.
- 8) Ventilate buildings, and other closed spaces. Do not house swine or other livestock until treatment has been absorbed, set, or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

**DIRECTIONS FOR USE IN FARM PREMISES, EQUINE FACILITIES, VEAL BARNES, RATITES FACILITIES, CALF PENS AND VEHICLES:**

- 1) Do not use in milking stalls, milking parlors, or milk houses.
- 2) Remove all animals and feed from the premises, vehicles, and enclosures.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from floors, surfaces, and from walls to ceiling of barns, pens, stalls, chutes, and other facilities occupied or traversed by animals.
- 4) Empty all troughs, racks, and other feeding and watering appliances.
- 5) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 6) Thoroughly saturate with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods. Allow to remain in contact with this solution for at least 10 minutes.
- 7) Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing manure in a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256). Allow to remain in contact for 10 minutes.
- 8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

**DIRECTIONS FOR USE IN POULTRY HOUSE:**

- 1) Remove all poultry and feeds from premises, trucks, coops, and crates.
- 2) Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
- 3) Empty all troughs, racks, and other feeding and watering appliances.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) for a period of 10 minutes.
- 6) Ventilate building, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
- 7) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

### **HATCHERY ROOMS, INCUBATORS AND HATCHERS, POULTRY HOUSES AND LIVESTOCK BUILDINGS BY FOGGING:**

All surfaces must be cleaned and disinfected in accordance with label directions prior to fogging. Fogging is not used as a sanitizing treatment. Close room off so fog is confined to room to be treated. Hatchery ventilation systems must remain on during fogging. Wear a dust/mist respirator when mixing the use solution and pouring it into the fogging apparatus.

**A) HATCHERY ROOMS:** Vacate all personnel from hatchery room to be fogged. Close room off so fog is confined to the hatchery room to be treated. Prepare a stock solution of one (1) part SYNERGIZE to forty-two (42) parts water (3 fluid ounces Synergize to 125 fluid ounces water). Fog this solution at a rate of 3.8 ounces per 10,000 cubic feet for the fogging times specified in the chart below. Contact your Preserve International representative to determine the recommended fogging schedule. Do not allow people to breathe or contact the fog. When fogging Synergize, re-entry intervals (REI) and personal protective equipment (PPE) are determined by the following hatchery room air exchange rates:

<b>ACH for Hatchery Rooms/ Incubators and Hatchers</b>	<b>Fogging Time</b>	<b>Re-entry Intervals (REI)</b>	<b>PPE Required</b>
8 Air Exchanges Per Hour	5 Minutes	25 Minutes	No PPE Required
12 Air Exchanges Per Hour	7.5 Minutes	15 Minutes	No PPE Required
16 Air Exchanges Per Hour	10 Minutes	10 Minutes	No PPE Required
20 Air Exchanges Per Hour	12.5 Minutes	10 Minutes	No PPE Required
24 Air Exchanges Per Hour	15 Minutes	10 Minutes	No PPE Required

Under no circumstances must the hatchery room be entered by unprotected persons before the listed re-entry intervals. If the hatchery room must be entered, before the listed re-entry intervals, then the individuals entering the room must wear a long sleeve shirt and pants and an approved NIOSH/MSHA full face piece respirator, such as the 3M 6700-6900 series, with an organic vapor cartridge, such as the 3M 6001, and a particulate filter, such as the 3M 5N11 & 3M 501 filter retainer.

### **B) INCUBATORS AND HATCHERS:**

Only for treatment of setters and hatchers after poultry/chicks/eggs have been removed. Not for treatment of hatchers which contain chicks/eggs. Prepare a stock solution of one (1) part Synergize to forty-two (42) parts water (3 fluid ounces Synergize to 125 fluid ounces water). Fog this solution at a rate of 3.8 ounces per 10,000 per cubic feet for the fogging times specified in the chart above, into setters and hatchers immediately after transfer. Repeat daily. Discontinue hatcher treatments approximately 24 hours before pulling the hatch. Do not allow people to contact or breathe this fog and do not enter machines until the fog has been exhausted. To do this, install permanent fogging nozzles in setters and hatchers and use an air compressor to disperse the sanitizing solution as a fog. It is also satisfactory to fog setters and hatchers with a 1:1000 solution of Synergize. If this is done, fog for 30 – 90 seconds once per hour or once every two hours.

### **C) POULTRY HOUSES AND LIVESTOCK BUILDINGS:**



After the house has been depopulated and cleaned as in “Directions for use in farm premises, equine facilities, veal barns, ratite facilities, calf pens and vehicles”, double check to be sure all people, poultry, livestock and pets have vacated the building. Close all windows, doors, curtains, etc. making the house as closed as possible. Prepare a stock solution of one (1) part Synergize to four (4) parts water (25 fluid ounces Synergize to 100 fluid ounces water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yards. The Fogger itself is placed just inside the door of the building to be treated, or the nozzle of the fogger is inserted through a suitable opening in the door or building. The opening must be large enough to accommodate the nozzle. After fogging, the building must be kept closed for twenty-four (24) hours. After twenty-four (24) hours, the fog must have settled and the house can now be opened and aired. The house must be opened for a minimum of twenty-four (24) hours before it is repopulated with poultry or livestock.

**NOTE FOR POULTRY HOUSES AND LIVESTOCK BUILDINGS:** The generated fog is very irritating to eyes, skin, and mucous membranes. Under no circumstances must a room or building be entered by anyone until the fog has completely settled. A reentry time of two (2) hours is required. If the building or room must be entered, then the individuals entering the building or room must wear a self-contained respirator approved by NIOSH/MSHA, goggles, long sleeve shirt and pants. If feeders and waterers were not removed from the premises during treatment, or were not adequately covered to prevent contact with the treatment, they must be washed with detergent and water before use for poultry or livestock.

#### **AIR WASHERS AND INDUSTRIAL SCRUBBING SYSTEMS/RECIRCULATING COOLING AND PROCESS WATER SYSTEMS:**

This product is used in industrial air washers and air washer systems which have mist-eliminating components.

SYNERGIZE must be added at the application rates described below to a water treatment system at a convenient point of uniform mixing such as a basin area. Addition is made intermittently (Slug Dose) or continuously. Badly fouled systems are shock treated with SYNERGIZE. Under these conditions, blowdown must be discontinued for up to 24 hours.

SYNERGIZE is used in industrial process water systems that contain ultra-filtration units and non-medical reverse osmosis membranes (Where approved for compatibility by the membrane manufacturer) and associated distribution systems.

#### **Intermittent (Slug Dose) Method:**

**Initial Dose:** When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved.

**Subsequent Dose:** When microbial control is evident, add 1.0 to 3.0 fluid ounces of SYNERGIZE per 100 gallons of water in the system weekly, or as needed to maintain control. Badly fouled systems must be cleaned before treatment is begun.

#### **Continuous Feed Method:**

**Initial Dose:** When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved.

**Subsequent Dose:** Maintain this treatment level by starting a continuous feed of 1.0 to 4.0 ounces per 100 gallons of water. Badly fouled systems must be cleaned before treatment is begun.

**VETERINARY PRACTICE (CLINICS)/ANIMAL CARE FACILITIES/ANIMAL LABORATORIES/ANIMAL LIFE SCIENCE LABORATORIES/ANIMAL RESEARCH CENTERS/ANIMAL QUARANTINE AREAS/ZOOS/PET SHOPS/KENNELS/ANIMAL HUSBANDRY/ANIMAL BREEDING FACILITIES/BREEDING AND GROOMING ESTABLISHMENTS/TACK SHOPS DISINFECTION DIRECTIONS:** For cleaning and disinfecting the following hard, non-porous surfaces: equipment not used for animal food or water, utensils, instruments, cages, kennels, stables, stalls and catteries. Remove all animals (and) feeds from areas to be treated, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) for a period of 10 minutes. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. At ½ ounce per gallon of water, in the presence of 1000 ppm of hardness and 5% organic load for a 10-minute contact time, Synergize was found to be effective against Canine Parvovirus.

*Staphylococcus aureus* A.T.C.C. 6538

*Pseudomonas aeruginosa* A.T.C.C. 15442

*Salmonella enterica* A.T.C.C. 10708

*Aspergillus fumigatus* A.T.C.C. 36607

Porcine Respiratory & Reproductive Syndrome Virus (PRRS)\*

*Salmonella enteritidis*

Avian Influenza (H3N2)\*

*Escherichia coli* F18

Porcine circovirus Type 2\*

Canine parvovirus A.T.C.C. VR-2016

*Salmonella choleraesuis*

### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage or disposal.

#### PESTICIDE STORAGE:

Store away from heat. Do not transfer to another container. Do not reuse empty container

#### PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**Container Handling:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available, or offer for reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

(For greater than 5 gallons) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Dispose of rinsate as noted in the pesticide disposal section. Repeat

this procedure two more times. (For 5 gallons or less) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Dispose of rinsate as noted in the pesticide disposal section. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

**General:** Consult Federal, State or local disposal authorities for approved alternative procedures.

**Alternate Brand Names:**

Synergize™ Cool  
Synergize™ NF  
Synergize™ NP  
Synergize™ NP-NF  
Synergize™ Orange  
Synergize™ Orange NF  
Companion

**Optional Marketing Statement(s):**

Preserve International is a wholly-owned subsidiary of Neogen Corporation.

**Logo(s):**

«Synergize logo»  
«Preserve International logo»  
«Neogen logo»  
«Neogen Flask icon»  
«American Flag icon»  
«PPE icon(s)»

**DOT SHIPPING NAME**

UN3264, Corrosive Liquid, Acidic, Inorganic, n.o.s. (Phosphoric Acid), 8, PG III

**Optional Warranty Statements:**

**DISCLAIMER:** To the extent permitted by applicable law, seller makes no representation or warranty, either express or implied, for results due to misuse, improper handling or improper storage of this material. Nor does Seller assume any responsibility for injury to persons, crops, animals, soil or property arising out of misuse, improper handling or improper storage of this material.

**OR**

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**LIMITED WARRANTY**

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To the extent permitted by applicable law, Preserve International and Neogen Corporation make no warranty concerning uses which extend beyond the use of the product under normal conditions in accord with the statements made on this label. To the extent permitted by applicable law,

Preserve International and Neogen Corporation shall not be liable for (1) any consequential, incidental or special damages related in any way to this product or its uses, or (2) any damages related in any way to resistance to pesticides.

OR

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**CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY**

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**NOTICE:** Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

To the extent permitted by applicable law Manufacturer and Seller warrant that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law this warranty does not extend to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or Manufacturer, and Buyer and User assume the risk of any such use. To the extent permitted by applicable law, MANUFACTURER AND SELLER MAKE NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

To the extent permitted by applicable law, in no event shall Manufacturer or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT PERMITTED BY APPLICABLE LAW THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF MANUFACTURER AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF THE MANUFACTURER OR SELLER, THE REPLACEMENT OF THE PRODUCT.

Manufacturer and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitations of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of Manufacturer.

For non-emergency (e.g., current product information),  
Call: 1-800-621-8829



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other Notification

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 66171-7	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Synergize™	PM#	
5. Name and Address of Applicant (Include ZIP Code) Preserve International 944 Nandino Blvd. Lexington, KY 40511 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: <input checked="" type="checkbox"/> EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

NOTIFICATION OF updated emergency telephone number and address, and addition of marketing claim/statement "Preserve International is a wholly-owned subsidiary of Neogen Corporation", additional logo(s) for Neogen Corporation, and optional warranty statements, pursuant to PR 98-10 for the product: Synergize™

## Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	
		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Tamra Barrick	Title Regulatory Specialist	Telephone No. (Include Area Code) 517-372-9200
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		8. Date Application Received (Stamped)
2. Signature TBarrick	3. Title Regulatory Specialist	
4. Typed Name Tamra Barrick	5. Date 10/25/2016	

DOCUMENTUM



October 25, 2016

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

RE: Synergize™  
EPA Reg. No. 66171-7

Gentlemen/Ladies:

Pursuant to PR-Notice 98-10, in regard to the subject product, we are hereby notifying the Agency of the several updates to the subject label as the result of Neogen's acquisition of Preserve International: updated address, updated emergency telephone number, additional marketing statements, additional Neogen logo(s), and optional warranty statements.

Following is my statement as required by PR-Notice 98-10:

This notification is consistent with the provisions of PR-Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with terms of PR-Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under Sections 12 and 14 of FIFRA.

Attached please find the completed application form marked for Notification, as well as a "before" and "after" label, with the additional items clearly marked. Identical revisions will be made to the Alternate Brand Names for the subject product: Synergize™ NF, Synergize™ NP, Synergize™ NP-NF, Synergize™ Orange, Synergize™ Orange NF, Companion.

If you should have any questions regarding this matter, please contact me at 517-372-9200 ext. 2223.

Sincerely,  
Preserve International

*TBarrick*

Tamra Barrick  
Regulatory Specialist

Enclosure(s)

DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

October 25, 2016

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

MS. TAMRA BARRICK  
PRESERVE INTERNATIONAL  
944 NANDINO BLVD.  
LEXINGTON, KY 40511-

PRODUCT NAME: SYNERGIZE  
COMPANY NAME: PRESERVE INTERNATIONAL  
OPP IDENTIFICATION NUMBER:  
EPA FILE SYMBOL: 66171-7  
EPA RECEIPT DATE: 10/25/16

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 31, at (703) 347-8028.

Sincerely,

A handwritten signature in black ink, appearing to be "mjh" or similar, written over a horizontal line.

Front End Processing Staff  
Information Services Branch  
Information Technology & Resources Management Division



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ISB In Processing : 66171-7 5993921 2016-10-25



Description: 66171-7 5993921 2016-10-25

From: Doc Admin

Received: 10/25/2016 12:36 PM

WorkFlow Instructions:

**cd\_14873\_993921 : Comments**

<u>Comment</u>	<u>Author</u>	<u>Date</u>
Non-PRIA. 332; Notification.	Kamarei, Donna	10/25/2016 12:36 PM

[Add](#)



# PROCESSING REQUEST

Reg # 66171-7

Decision # 511819

Description: To update and Add an alternate CSFs

Electronic Label & Letter  
(see PPLS):

OR

Non Electronic  
Label & Letter  
(Scanning required):

☐ Dated:

☐ Dated:

\*\*\*Only one label type should be selected\*\*\*

Other Materials Sent (see jacket):

X New CSF(s) Dated: 12/17/2015

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Karen M. Leavy

Division: AD

Phone: 308-6237

Date: 01/13/2016



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

December 21, 2015

Mr. Gary E. Gaumer  
President for,  
Preserve International  
P. O. Box 17003  
Reno, NV 89115

Subject: CSF Notification per PRN 98-10 – to add an alternate CSF  
Product Name: Synergize  
EPA Registration Number: 66171-1  
Application Date: November 18, 2015  
Decision Number: 511819

Dear Mr. Gaumer:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The CSFs submitted with your application have been stamped "Notification" and placed in our files.

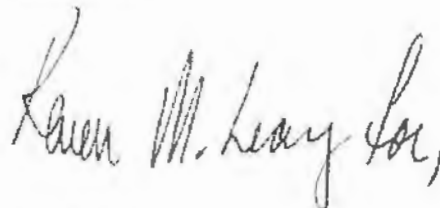
Please note that the record for this product currently contains the following CSFs:

- Basic CSF Synergize dated 06/09/2014
- Alternate CSF, Synergize AF-Int dated 12/17/15
- Alternate CSF, Synergize NF dated 12/17/15
- Alternate CSF, Synergize NP dated 12/17/15
- Alternate CSF, Synergize NP-NF dated 12/17/15
- Alternate C. F., Synergize Orange dated 12/17/15
- Alternate C. F., Synergize Orange NF dated 12/17/15

Any CSFs other than those listed above are superseded/no longer valid.

If you have any questions, please contact Karen M. Leavy at (703)-308-6237 or by email at [Leavy.Karen@epa.gov](mailto:Leavy.Karen@epa.gov).

Sincerely,

A handwritten signature in dark ink, appearing to read "Karen M. Leavy", with a stylized flourish at the end.

Eric Miederhoff  
Product Manager 31  
Regulatory Management Branch I  
Antimicrobials Division (7510P)  
Office of Pesticide Programs



✓ **World Headquarters** P.O. Box 17003, Reno, NV 89511 • Bus: (775) 853-9776 • Fax: (775) 406-3413 • USA: (800) 995-1607  
**Tennessee Operation** 1213 Empire Avenue, Memphis, TN 38107 • Bus: (901) 272-0031 • Fax: (901) 726-6446  
**California Operation** 1355 Paulson Road, Turlock, CA 95380 • Bus: (209) 664-1607 • Fax: (209) 664-1728

November 18, 2015

Mr. Eric Miederhoff  
Office of Pesticides Programs (7504C)  
United States Environmental Protection Agency (NOTIFICATION)  
Ariel Rios Building  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460

Dear Mr. Miederhoff:

Attached to this cover are the documents to support Preserve International's desire to register, via notification, an additional alternate formula for our product Synergize, EPA registration number 66171-7. The Alternate formula identifier for this formula is: Synergize AF/int.

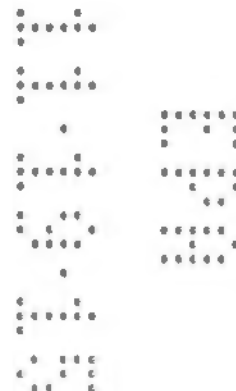
This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement or formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statements to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

If I may be of further assistance, please feel free to contact me at 775-853-9776

Thank you for your time and consideration.

Sincerely,  
Preserve International

Gary E. Gaumer  
President



Receipt for Section 3

S: 977444

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Notification

Fee For Service: ☐ Yes ☒ No

Company: 66171 PRESERVE INTERNATIONAL

V

Risk Manager: Antimicrobials Division, Risk Management Team 31

Product #: 66171-7

Product Name: SYNERGIZE

Override#:

Me Too Section3:

Me Too Product Name:

Application Date: 18-Nov-2015

OPP Rec'd Date: 19-Nov-2015

Front End Date: 19-Nov-2015

Risk Manager Send Date: 19-Nov-2015

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Notification consistent with provisions of PR Notice 98-10

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

View/Edit

New Ingredient Request Date:

New Ingredient Received Date:

Attention PM Team:

Additional Confidential  
Statements of Formula (CSFs)  
can be found in earlier jacket  
volumes including imaged  
volumes.

